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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,940	03/26/2004	Alisa Ann Ivory	9191ML	1918

27752 7590 12/19/2006
THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
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EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.	Applicant(s)	
10/810,940	IVORY ET AL.	
Examiner	Art Unit	
Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1 - 13 in the reply filed on September 29, 2006 is acknowledged. The traversal is on the ground(s) that the groups are related and there is not a serious burden of search due to classification in the same class. This is not found persuasive because while the inventions are related and may overlap in search, an overlapping search is not a coextension search. Thus a reference that would anticipate one group may not anticipate or even make obvious the invention of another group. Thus a serious burden exists to examine all groups together.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14 – 19 are withdrawn from consideration; claims 1 – 13 have been examined on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 – 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 11 and 12 recite the term “safe and effective amount”. However, this phrase renders the claims and their dependents indefinite because the specification states that the effective amounts can be adjusted depending on the use and desired effect of the edible film. Since there are multiple uses and effects disclosed in the specification, it is unclear what amounts are deemed effective for what purpose, which renders the limitation vague and indefinite.

In claims 3, 4, 8 and 9, “the level” lacks sufficient antecedent basis.

Claims 12 and 13 are rendered vague and indefinite for reciting “less than about 1%” and “less than about 0.5%” because it is unclear if the composition must contain some amount of a surfactant or if the claim allows for no amount of surfactant to be present in the composition. For purposes of examination, the limitation has been interpreted to include 0%, or no amount, of surfactant.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3 – 4 and 12 – 13 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Barkalow et al. (US 2002/0131990 A1).

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Applicant claims an edible film composition comprising safe and effective amounts of a fiber agent selected from indigestible dextrin, purified wood cellulose, psyllium, or mixtures thereof; a film forming agent; plasticizing agent; and a flavoring agent. The fiber is present in an amount of about 1 – 15%, or about 5 – 10%. Applicant additionally claims an edible film composition comprising safe and effective amounts of a fiber agent selected from indigestible dextrin, purified wood cellulose, psyllium, or mixtures thereof; a film forming agent; plasticizing agent; and a flavoring agent; wherein the film rapidly dissolves in the oral cavity and has less than 1% of a surfactant; or less than 0.5% surfactant.

Barkalow teaches an edible film composition comprising bulk filler agents, film forming agents, plasticizing agents and flavoring agents (0006,0018) wherein the bulk fillers may be wood cellulose (0048) and is present at 10 – 90% (0007,0009). The composition does not require surfactant, thus contains less than 1 or 0.5% surfactant.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow in view of Yatka et al. (US 5458892 A).

Applicant claims an edible film composition comprising safe and effective amounts of a fiber agent selected from indigestible dextrin, purified wood cellulose, psyllium, or mixtures thereof; a film forming agent; plasticizing agent; and a flavoring agent. The fiber is present in an amount of about 1 – 15%; or about 5 – 10%. The fiber is indigestible dextrin with a length of about 15 – 50 microns or 20 – 35 microns. The film dissolves rapidly in the oral cavity; the fiber agent encapsulates the flavoring agent; the film forming agent is present at about 2 – 75%, or 15 – 40% and is selected from hydroxypropyl cellulose, hydroxypropyl methyl cellulose and mixtures thereof. The composition further comprises a safe and effective amount of a vegetable oil. Applicant additionally claims an edible film composition comprising safe and effective amounts of a fiber agent selected from indigestible dextrin, purified wood cellulose, psyllium, or mixtures thereof; a film forming agent; plasticizing agent; and a flavoring agent; wherein the film rapidly dissolves in the oral cavity and has less than 1% of a surfactant; or less than 0.5% surfactant.

Barkalow teaches an edible film composition comprising bulk filler agents, film forming agents, plasticizing agents and flavoring agents (0006,0018) wherein the bulk fillers may be wood cellulose (0048), the film forming agents are hydroxypropyl methyl cellulose (0043). The composition may additionally contain vegetable oils (0065). The bulking agent and film forming agents are present at 10 – 90% (0007,0009) and the composition rapidly dissolves (0032).

Barkalow does not teach the composition wherein the bulk filler agent is indigestible dextrin with the claimed length; or wherein the bulking agent encapsulates the flavoring agent. However, at the time of the claimed invention, indigestible dextrin was a known and used bulk filler agent in the art. In support, Yotka teaches a bulking agent that is indigestible dextrin with the claimed length (col.1 line 44-57, col.3). In addition, Yotka teaches that the indigestible dextrin can be dried with flavors to encapsulate the flavor (col.2 line 25-36, col.6 line 13-23). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the indigestible dextrin of Yotka as the bulk filling agent of Barkalow, since it was a recognized bulk filler in the art. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Yotka to substitute indigestible dextrin as the bulk filler in the composition with a reasonable expectation for successfully obtaining the functional edible film of Barkalow.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

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is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1 – 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 12 of copending Application No.

10/810,939. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims differ by amounts of agents, or by parameters such as fiber length and/or viscosity. At the time of the claimed invention, one of ordinary skill in the art would have been motivated to further characterize the specific parameters of the film, to include fiber length and viscosity, as a matter of routine experimentation and practice.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis
Primary Examiner
Art Unit 1651



December 8, 2006